

CLAIMS

1. A process for the preparation of sertraline hydrochloride by
 - a. Suspending/dissolving sertraline base or acetate in suitable solvents
 - 5 b. Adjusting the pH of the mixture with hydrogen chloride either in anhydrous form or aqueous form at elevated temperatures ranging from 25°C to 65°C
 - c. Cooling the reaction mixture
 - d. isolating and drying to obtain sertraline hydrochloride.
- 10 2. A process according to claim 1, to make sertraline hydrochloride form II by
 - a. Suspending/dissolving sertraline acetate in suitable solvents
 - b. Adjusting the pH of the mixture with hydrogen chloride gas at elevated temperatures ranging from 40°C to 65°C
 - 15 c. Cooling the reaction mixture
 - d. Isolating and drying the sertraline hydrochloride to obtain form II.
3. A process according to claim 2, wherein the cooling is done gradually over a couple of hours to bring the temperature from 60°C to 25°C-20°C.
- 20 4. A process according to claim 2 or 3, wherein the cooling is done over more than 2 hours.
5. A process according to claim 1 to make sertraline hydrochloride form III by
 - 25 a. Suspending/dissolving sertraline acetate in suitable solvents
 - b. Adjusting the pH of the mixture with hydrogen chloride gas at elevated temperatures ranging between 40°C to 65°C
 - c. Cooling the reaction mixture
 - d. Isolating and drying the sertraline hydrochloride to obtain form III.
- 30 6. A process according to claim 5, wherein the cooling is done rapidly over a few minutes to bring the temperature from 60°C to 15°C-20°C.

7. A process according to claim 5 or 6, wherein the cooling is done in less than 1 hour.
8. A process according to claim 1 to make sertraline hydrochloride form IV by
- 5 a. Suspending/dissolving sertraline acetate in suitable solvents
- b. Adjusting the pH of the mixture with hydrogen chloride gas at elevated temperatures ranging between 40°C to 65°C
- c. Cooling the reaction mixture
- d. Isolating and drying the sertraline hydrochloride to obtain from IV.
- 10 9. A process according to claim 8, wherein the sertraline acetate is suspended/dissolved in solvents such as methanol, ethanol, isopropanol, ethyl acetate, or mixtures thereof.
- 15 10. A process according to claim 8 or 9, wherein the solvent used is isopropanol.
11. A process according to claim 8, 9 or 10, wherein the cooling is done rapidly to bring the temperature from 60°C to 25°C - 20°C.
- 20 12. A process according to claim 8, 9, 10 or 11, wherein the cooling is done in from 30 minutes to 1 hour.
13. A process according to any one of claims 8 to 12, wherein the sertraline hydrochloride form IV is dried in a fluid bed drier.
- 25 14. A process according any one of claims 2 to 7, wherein the sertraline acetate is suspended/dissolved in solvents such as methanol, ethanol, isopropanol ethyl acetate, toluene or mixtures thereof.
- 30 15. A process according to any one of claims 2 to 7, wherein the solvent used is a mixture of isopropanol and toluene
16. A process according to claim 15, wherein toluene is present between 2 to 8% by

weight of the total volume of solvent.

17. A process according to any of claims 2 to 16, wherein the pH of the mixture is adjusted to a value from 1-2.

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18. A process according to claim 17, wherein the pH is adjusted at a temperature from 45°C to 65°C.

19. A process according to claim 1 to make sertraline hydrochloride form V by

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- a. Suspending/dissolving sertraline acetate in suitable solvents
- b. Adjusting the pH of the mixture with aqueous hydrochloric acid at ambient temperatures ranging between 30°C to 25°C
- c. Isolating and drying the sertraline hydrochloride to obtain form V.

15 20. A process according to claim 19, wherein the sertraline acetate is suspended/dissolved in solvents such as methanol, ethanol, isopropanol, ethyl acetate or water mixtures thereof.

21. A process according to claim 18, wherein the solvent used is water.

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22. A process according to claim 19, 20 or 21, wherein the pH of the mixture is adjusted to a value from 1-2.

23. A process according to claim 22, wherein the pH is adjusted at a temperature
25 from 25°C-35°C.

24. A process according to claim 1 to make sertraline hydrochloride Form V by

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- a. Suspending/dissolving sertraline base in suitable solvents
- b. Adjusting the pH of the mixture with aqueous hydrogen chloride
- c. Cooling the reaction mixture
- d. Isolating and drying the sertraline hydrochloride to obtain form V.

25. A process according to claim 24, wherein the sertraline base is

suspended/dissolved in acetic acid.

26. A process according to claim 24 or 25, wherein the solvent used is acetic acid.

5 27. A process according to claim 24, 25 or 26, wherein the pH of the mixture is adjusted to a value from 1-2.

28. A process according to claim any one of claims 24 to 27, wherein the cooling is done gradually to bring the temperature from 30°C to 5°C - 0°C.

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29. Sertraline hydrochloride produced by a process according to any one of claims 1 to 28.

30. Form II sertraline hydrochloride produced by a process according to any one of
15 claims 2 to 4 or 14 to 18.

31. Form III sertraline hydrochloride produced by a process according to any one of claims 5 to 7 or 14 to 18.

20 32. Form IV sertraline hydrochloride produced by a process according to any one of claims 8 to 13, 17 or 18.

33. Form V sertraline hydrochloride produced by a process according to any one of claims 19 to 28.

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34. A pharmaceutical composition comprising sertraline hydrochloride according to claim 29 in combination with a pharmaceutically acceptable carrier.

35. A pharmaceutical composition comprising sertraline hydrochloride Form II
30 according to claim 30 in combination with a pharmaceutically acceptable carrier.

36. A pharmaceutical composition comprising sertraline hydrochloride Form III according to claim 31 in combination with a pharmaceutically acceptable carrier.

37. A pharmaceutical composition comprising sertraline hydrochloride Form IV according to claim 32 in combination with a pharmaceutically acceptable carrier.
- 5 38. A pharmaceutical composition comprising sertraline hydrochloride Form V according to claim 33 in combination with a pharmaceutically acceptable carrier.